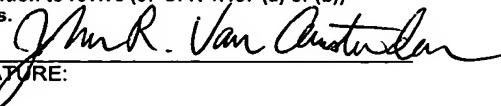


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| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 | | ATTORNEY'S DOCKET NUMBER H0666.70007US00 |
| INTERNATIONAL APPLICATION NO. PCT/JP2003/003804 | INTERNATIONAL FILING DATE 27 March 2003 (27.03.2003) | PRIORITY DATE CLAIMED n/a |
| TITLE OF INVENTION MEDICINAL ORAL PREPARATIONS FOR COLON DELIVERY, MEDICINAL ORAL PREPARATIONS FOR TREATING COLON CANCER AND MEDICINAL ORAL PREPARATIONS FOR TREATING COLITIS | | |
| APPLICANT(S) FOR DO/EO/US SATO, Shuji; GOTO, Takeshi; TANIDA, Norifumi; MENO, Tatsuya; YOSHINAGA, Takaaki and YONEMURA, Keishi | | |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: | | |
| <ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. 2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371 (f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input checked="" type="checkbox"/> The US has been elected (Article 31). 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input checked="" type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)). <ol style="list-style-type: none"> a. <input checked="" type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)) <ol style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input checked="" type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)). 9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)). | | |
| Items 11 to 20 below concern document(s) or information included: | | |
| <ol style="list-style-type: none"> 11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input checked="" type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input checked="" type="checkbox"/> A preliminary amendment. 14. <input checked="" type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A power of attorney and/or change of address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. 18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 20. <input checked="" type="checkbox"/> Other items or information: PCT Published Application, ISR (English translation), PCT/IB/301;304;308;332 forms; Express Mail No:EV717508065US IPER (w/English translation) | | |

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|--|--------------|---|---------------------------|--------------|--|
| U.S. APPLICATION NO. (if known, see 37 CFR 1.15) | | INTERNATIONAL APPLICATION NO. | ATTORNEY'S DOCKET NUMBER: | | |
| 107550586 | | PCT/JP2003/003804 | H0666.70007US00 | | |
| The following fees have been submitted | | CALCULATIONS | | PTO USE ONLY | |
| 21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.492(a)) \$300 | | \$ 300.00 | | | |
| 22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$ 0 All other situations \$200 | | | | | |
| 23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$ 0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB \$400 All other situations \$500 | | \$ 200.00 | | | |
| TOTAL OF 21, 22 and 23 = | | \$ 400.00 | | | |
| <input checked="" type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | \$ 900.00 | | | |
| Total Sheets | Extra sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE | | |
| 47 - 100 = | /50 = | | x \$250.00 | 0.00 | |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492 (e)). | | \$ | | | |
| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE | | |
| Total claims | 36 - 20 = | 16 | x 50.00 | \$ 800.00 | |
| Independent claims | 3 - 3 = | 0 | x 0.00 | \$ 0.00 | |
| MULTIPLE DEPENDENT CLAIM(s) (if applicable) | | + | \$ | | |
| TOTAL OF ABOVE CALCULATIONS = | | \$ 1700.00 | | | |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½. | | \$ | | | |
| SUBTOTAL = | | \$ | | | |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492 (f)). | | \$ | | | |
| TOTAL NATIONAL FEE = | | \$ 1700.00 | | | |
| Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property | | \$ 40.00 | | | |
| TOTAL FEES ENCLOSED = | | \$ 1740.00 | | | |
| | | Amount to be refunded: | \$ | | |
| | | Amount to be charged: | \$ | | |
| a. <input checked="" type="checkbox"/> A check in the amount of \$ 1740.00 to cover the above fees is enclosed. | | | | | |
| b. <input type="checkbox"/> Please charge my Deposit Account No. 23/2825 in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed. | | | | | |
| c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 23/2825. A duplicate copy of this sheet is enclosed. | | | | | |
| d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. | | | | | |
| NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the International Application to pending status. | | | | | |
| SEND ALL CORRESPONDENCE TO: | | | | | |
| Wolf, Greenfield & Sacks, P.C. 600 Atlantic Avenue Boston, Massachusetts 02210-2206 Tel. (617) 646-8000 | | | | | |
| SIGNATURE:  | | | | | |
| John R. Van Amsterdam | | | | | |
| CUSTOMER NUMBER: 23628 | | | | | |
| NAME _____ | | | | | |
| 40,212 | | | | | |
| REGISTRATION NUMBER _____ | | | | | |

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re International Application of SATO, Shuji et al

International Serial No.: PCT/JP2003/003804

International Filing date: March 27, 2003

For: MEDICINAL ORAL PREPARATIONS FOR COLON DELIVERY,
MEDICINAL ORAL PREPARATIONS FOR TREATING COLON
CANCER AND MEDICINAL ORAL PREPARATIONS FOR TREATING
COLITIS

VERIFICATION OF TRANSLATION

Honorable Commissioner of Patents and Trademarks
Washington D.C. 20231

Sirs:

KUZUWA, Kiyoshi residing at T & T Bldg., 8-21, Tomihisa-cho, Shinjuku-ku, Tokyo, Japan, declares:

(1) that he knows well both Japanese and English languages;

(2) that he translated the above-identified International Application from Japanese to English;

(3) that the attached English translation is a true and correct translation of the above-identified International Application to the best of his knowledge and belief; and

(4) that all statements made of his own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 USC 1001, and that such false statements may jeopardize the validity of the application or any patent issuing thereon.

August 24, 2005

Date

K. K. T.
KUZUWA, Kiyoshi